CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-488

Microbiology Review(s)

Product Quality Microbiology Review
Review for HFD-580

12 Dec. 2002

NDA:	**21-488-BZ**
Drug Product Name	
Proprietary:	ELIGARD™ 30mg
Non-proprietary:	Leuprolide Acetate for Injectable Suspension
Drug Product Classification:	
Review Number:	2
Subject of this Review	
Submission Date:	November 15, 2002
Receipt Date:	November 18, 2002
Consult Date:	November 19, 2992
Date Assigned for Review:	December 2, 2002
Submission History (for amendments only)	
Date(s) of Previous Submission(s):	April 13, 2002
Date(s) of Previous Micro Review(s):	November 27, 2002
Applicant/Sponsor	
Name:	Atrix Laboratories Inc
Address:	2579 Midpoint Dr. Fort Collins, CO 80525-4417
Representative:	Johanna Matz
Telephone:	970-482-5868.
Name of Reviewer:	Stephen E. Langille, Ph.D.
Conclusion:	Recommended for approval

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUPPLEMENT:** N/A

2. **SUPPLEMENT PROVIDES FOR:** N/A

3. **MANUFACTURING SITE:** /

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**

- Subcutaneous Injection
- 30.0 mg

5. **METHOD(S) OF STERILIZATION:** /

6. **PHARMACOLOGICAL CATEGORY:** Palliative treatment for prostrate cancer

B. **SUPPORTING/RELATED DOCUMENTS:**
The first review of NDA 21-488 was completed on 11-27-02. Reviews for NDA 21-379, 21-379-BZ and 21-379-AZ were completed on 5-15-02, 5-31-02, and 7-22-02 respectively. The Applicant also submitted NDA 21-488 amendment 5 on December 10, 2002 to clarify the nature of the container/closure system used for the various ELIGARD® products.

C. **REMARKS:** NDA 21-379 was submitted in support of the 22.5 mg dosage of ELIGARD. This dosage is also manufactured at [redacted] and uses the same 2-syringe container system as the 30 mg dosage (subject of this review). The microbiology information provided amendment 21-488-BZ is in response to the written comments provided for the review of NDA 21-379

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Executive Summary

I. Recommendations

A. Recommendation on Approvability -
NDA 21-488-BZ is recommended for approval from the standpoint of microbial product quality.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -
The drug product is packaged in two separate syringes and mixed prior to injection. Syringe A contains the ATRIGEL delivery system and syringe B contains — leuprolide acetate. Syringe A and its contents are —
— Syringe B is — with leuprolide acetate

B. Brief Description of Microbiology Deficiencies -
No deficiencies were identified based upon the information provided.

C. Assessment of Risk Due to Microbiology Deficiencies -

III. Administrative

A. Reviewer's Signature /S/

B. Endorsement Block
Stephen E. Langille, Ph.D.
Peter Cooney, Ph.D.

C. CC Block
In DFS

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/s/

Stephen Langille
12/18/02 04:00:12 PM
MICROBIOLOGIST

Peter Cooney
12/18/02 04:09:00 PM
MICROBIOLOGIST

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/s/

Stephen Langille
12/18/02 04:00:12 PM
MICROBIOLOGIST

Peter Cooney
12/18/02 04:09:00 PM
MICROBIOLOGIST